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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/465,322	06/05/1995	HANS E. SODERLUND	A28203-A-FWC	1828

7590

02/03/2003

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EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 02/03/2003

39

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/465,322

Applicant(s)

SODERLUND ET AL.

Examiner

Carla Myers

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 97-116 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 97-116 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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1. This action is in response to the amendment of Paper No. 38, filed October 25, 2002. Applicants amendments and arguments set forth in Paper No. 38 have been fully considered but are not persuasive to overcome all grounds of rejection. All rejections not reiterated herein are hereby withdrawn. This action is made final.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY  
APPLICANTS AMENDMENTS TO THE CLAIMS:

2. Claims 97-116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the amendment to the claims to recite kits for "detecting the presence or absence of one or more specific nucleotides at a predetermined position." The specification as originally filed provides support for methods and kits for the detection of a variable nucleotide or a point mutation and methods and kits for detecting a specific nucleotide variation at a defined site. However, the specification does not provide support for the claims as amended to encompass detecting the presence or absence of one or specific nucleotides. Additionally, with respect to claims 107-116, the specification does not provide basis for the concept of an admixture containing at least one deoxynucleotide and at least one labeled chain-terminating nucleotide wherein "each deoxynucleotide of the admixture of nucleoside triphosphates being complementary to a nucleotide which differs from any nucleotide to which a chain-terminating nucleotide analogue of the admixture is complementary." While the

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specification exemplifies methods in which the admixture comprises labeled dTTP, ddCTP and ddGTP or the admixture comprises labeled dCTP, ddTTP and ddGTP, these specific embodiments do not provide support for the more broadly claimed admixture set forth in (c) of claim 107.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 97-106 are rejected under 35 U.S.C. § 103 as being unpatentable over Holmes (WO 98/09282; cited in the IDS of Paper No. 27).

Holmes et al (pages 11-12) disclose methods for sequencing DNA wherein the methods require the use of the reagents of a primer, a polymerase and an admixture comprising labeled deoxynucleotides and "at least two chain-terminating nucleotide analogues." It is noted that the claims do not require that each of the at least two chain-terminating nucleotides are different from one another (e.g., ddATP and ddGTP). Accordingly, the claims are considered to be inclusive of admixtures comprising multiple copies of chain-terminating nucleotides (e.g., 25uM ddATP).

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Holmes also teaches amplifying a target nucleic acid prior to sequencing wherein said amplification requires the use of a pair of primers such that one of the primers is labeled with an attachment moiety (page 7). The reference teaches labeling the nucleotides with radioactive isotopes or fluorescent moieties (page 5) and exemplifies the use of primers of 18 nucleotides. Holmes does not teach packaging the reagents required to practice the sequencing method in a kit. However, reagent kits for performing diagnostic methods were conventional in the field of molecular biology at the time the invention was made. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the primer, polymerizing agent, and admixture of dideoxynucleotides and labeled nucleotides in a kit for the expected benefits of convenience and cost-effectiveness for practioners in the art wishing to perform the disclosed method of sequencing target nucleic acids.

With respect to claim 98, Holmes teaches immobilizing the strand of DNA to be sequenced but does not teach including an attachment moiety in the primer used for sequencing. However, Holmes also teaches the concept of labeling primers and of incorporating nucleotides having labels attached thereto that can serve as a means for immobilizing the extended nucleic acid (pages 3-4). Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Holmes so as to have included an attachment moiety in the primer for sequencing in order to have provided an alternative means for capturing and separating the sequencing products.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

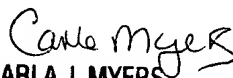
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

January 27, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER